

# **Legal Updates 2018: Public Health Law; Government Regulation of Behavior**



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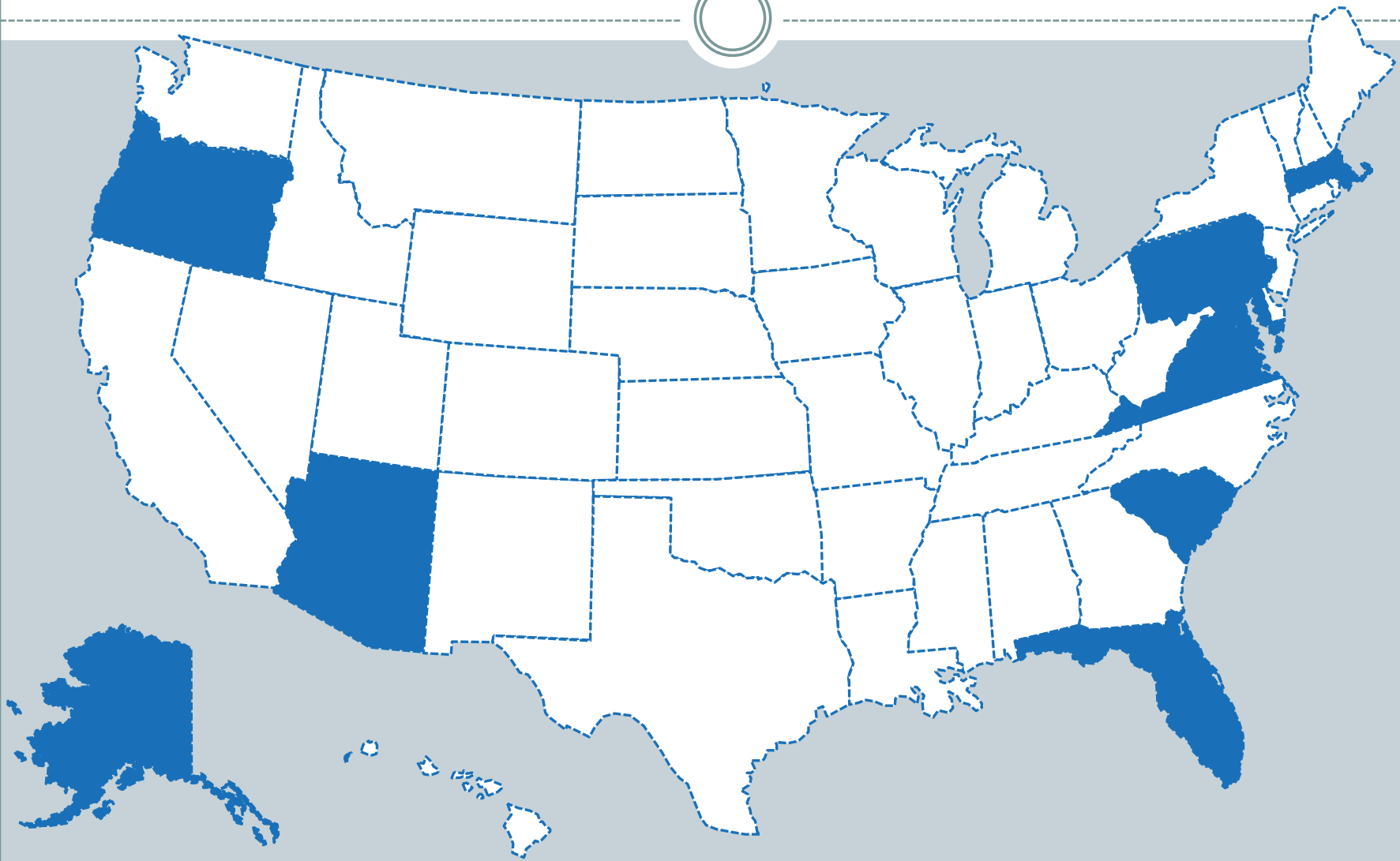
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# Opioid Epidemic



- **Increase in overdose deaths in 2018**
  - *NIH Overdose Death Rates*, at <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>
  - *CDC, Provisional Overdose Death Counts*, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

# State Declarations of Opioid Emergencies



# State Declarations of Opioid Emergencies



- **Extend access to naloxone to reduce overdose deaths**
- **Enhance surveillance and reporting of overdose death**
- **Mandate Prescription Drug Monitoring Programs by physicians and pharmacists**
- **Garner federal grants for programs, treatment services, and prevention**

# Declaration of National Emergency



- **July 21, 2017: Presidential Commission recommends declaration of national emergency**
- **August 10, 2017: Trump states intention to declare national emergency**
- **October 26, 2017 - presents: Declaration of public health emergency; NOT a national emergency**



# Opioid Litigation



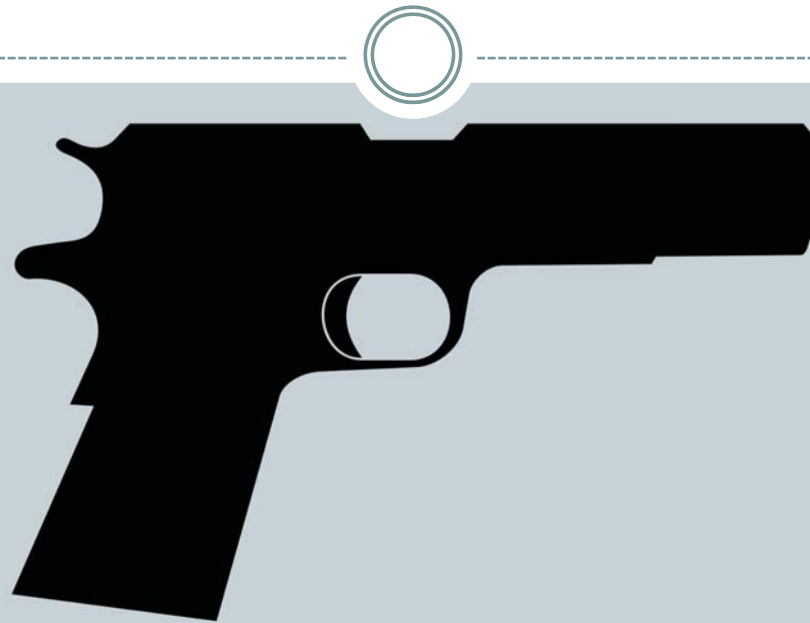
- **Beginning stages**
- **Trials to begin in fall 2019**
- **Any settlements estimated to be lower than 1998 big tobacco settlements (\$206 billion)**



# Federal Legislation

- **September 17, 2018: Congress passes the Opioid Crisis Response Act of 2018**
  - **STOP Act**
  - **FDA limited packaging**
  - **Establishes interagency task force**
  - **Allows Medicaid to pay for residential addiction treatment**
  - **Allows Medicare to pay for methadone treatment**
  - **Pay for research for opioid alternatives**
  - **Authorize funds for a “plan of safe care” for babies born with opioid dependence**

# Gun Violence as Public Health Crisis



For data on gun violence over time, see Wintemute G, *Gun Violence in the United States*, 379 NEJM 1193-1196 (2018), at <https://www.nejm.org/doi/full/10.1056/NEJMp1807277#.W65DCSqzmiw>



# Gun Violence as Public Health Crisis



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## AMA Recommends New, Common-sense Policies to Prevent Gun Violence

For immediate release: Jun 12, 2018



CHICAGO – Shocked by the massacre at the Pulse Nightclub in Orlando in 2016, the American Medical Association (AMA) declared that gun violence in America is a public health crisis. Since then, tens of thousands more Americans have died in gun violence, in mass shootings and suicides, incidents that often stunned

Source: AMA at <https://www.ama-assn.org/ama-recommends-new-common-sense-policies-prevent-gun-violence>

# Suicide as a Public Health Emergency



- **Steady increase in suicide rates**
- **Highlighted by the public suicides of Kate Spade and Anthony Bourdain**
- *See Hedegaard H, Curtin S, Warner M. **Suicide Rates in the United States Continue to Increase. National Center for Health Statistics; 2018.***

# Gun Violence and Research



- **Dickey Amendment prevents HHS from using funds “to advocate or promote gun control”**

# Gun Violence and Research



- **Dickey Amendment prevents HHS from using funds “to advocate or promote gun control”**
- **2018 omnibus spending bill added language regarding gun research; no change to Dickey language**



# Violence Against Women Act



- **Set to expire Oct. 1, 2018**
- **Extended until December 7...**
- **?**

# Hurricanes Florence, Michael, Maria, Nate...



- Federal and state emergency/public health



# Hurricanes Florence, Michael, Maria, Nate: Legal Issues



- **Emergency declarations and powers**
- **Emergency care during crisis (pregnant patients, dialysis patients, emergency patients, surgical patients, etc.)**
- **Mass torts, etc. from carcinogens, mold...**
- **Flood insurance**
- **Property issues**
- **Federal emergency management agency programs**
- **Lost jobs**
- **Food and shelter (CDC)**
- **Disparate impact, particularly for vulnerable populations**
- **Maintenance of the rule of law**

# Hurricanes Florence, Michael, Maria, Nate: Legal Issues



- **For more, see:**

[https://www.networkforphl.org/\\_asset/rfg7c7/Hurricanes-Harvey--Irma---Network-Primer-v2.pdf](https://www.networkforphl.org/_asset/rfg7c7/Hurricanes-Harvey--Irma---Network-Primer-v2.pdf)





# Marijuana Regulation



- 9 states have legalized recreational and medical marijuana
- 21 others have legalized marijuana for medical use only
- November elections:
  - 2 states have ballot initiatives in November that, if passed, would legalize adult marijuana use
  - 2 additional states have ballot initiatives that would legalize medical marijuana
- See *National Conference of State Legislatures*, at <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>



# Marijuana Regulation



- **No steps to legalize at the federal level**
- **January 2018: AG Sessions rescinds the Cole Memorandum (2013)**



# E-Cigarette Regulation



- **Sept. 12, 2018: FDA Commissioner calls use of e-cigarettes by minors an “epidemic”**
- **Oct. 3: FDA raid of Juul’s offices**
- **60 day deadline to demonstrate plan to restrict access to minors**
- **Oct. 12: FDA warning letters to manufacturers**





# Vaccines



- **October 2018: CDC reports rate of non-vaccination has increased from .3% from children born in 2001 to 1.3% for those born in 2015.**
- **Found “several opportunities for improvement.”**
- **See *CDC, Vaccination Coverage Among Children Aged 19-35 months – United States, 2017*, at [https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm?s\\_cid=mm6740a4\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm?s_cid=mm6740a4_w)**



# Vaccines



- Lawsuit (*Brown v. Smith*) challenged CA's 2015 mandatory vaccination law (SB277), which eliminated personal belief exceptions
- July 2018: California state court upheld the law
  - The law did not violate freedom of religion
  - The law did not violate right to an education

# Workplace Wellness



- 2016 Lawsuit (*AARP v. EEOC*) alleging that EEOC's workplace wellness regulations alleged that penalty for non-participation makes wellness plans not "voluntary"
- Oct. 2018: regulations vacated, as of January 1, 2019



v.



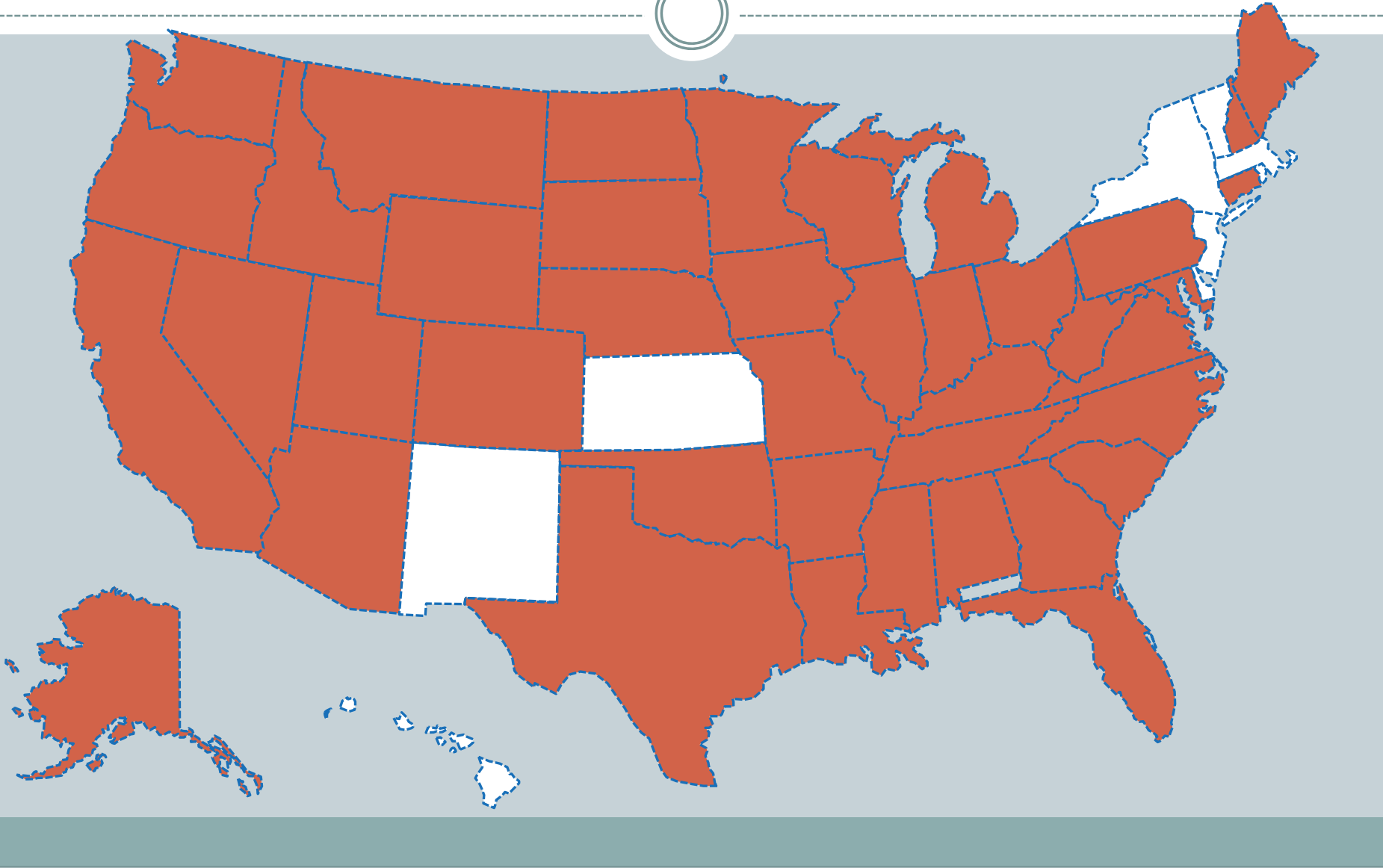
# Flint



- **Michigan HHS director to stand trial for death of two men**



# State Right to Try Laws





# Federal Right to Try



- **May 2018: Right to Try law passed**
  - “eligible” (terminally ill) patients
  - Drug must have completed Phase I trials
  - No obligation by drug developer to provide access
- **Intended to be parallel pathway to FDA’s expanded access**



# Affordable Care Act



- *Texas v. United States*

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- *Texas v. United States*
- Medicaid Work Requirements (and *Stewart v. Azar*, etc.)
- Final rule approving short-term, limited duration coverage (“junk plans”) up to 36 months
- Scale back of outreach and education